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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/540716

Applicant's or agent's file reference VMAFRIPCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/39472	International filing date (day/month/year) 10 December 2003 (10.12.2003)	Priority date (day/month/year) 10 December 2002 (10.12.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 7/00 and US Cl.: 424/401			
Applicant VENTURE MANAGEMENT ALLIANCE, LLC			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>6</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 07 July 2004 (07.07.2004)		Date of completion of this report 15 November 2004 (15.11.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer <i>Valerie Bell-Harris</i> BLESSING FUBARA Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/39472

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed.
- ☒ the description:
 pages 1-27 as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the claims:
 pages NONE, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages 30-35, filed with the letter of 22 October 2004 (22.10.2004)
- ☒ the drawings:
 pages 1-6, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/39472**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims 4-15, 18-30, 32-55 and 58-62	YES
	Claims 1, 3 and 17	NO
Inventive Step (IS)	Claims 4-15, 18-30, 32-55 and 58-62	YES
	Claims 1, 3 and 17	NO
Industrial Applicability (IA)	Claims 1, 3-15, 17-30, 32-55 and 58-62	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Applicants' response to the written opinion opposes the holding of claims 1, 3 and 17 as lacking novelty over PAHLCK et al (US 5,320,835) on the grounds that claim 1 as amended recites "aqueous carrier" in section a of claim 1 while the prior art does not disclose aqueous carrier because according to applicants, the microcapsules of the PAHLCK are formed from aqueous soluble gelatin and gum Arabic, which would dissolve in aqueous carrier.

Applicants' argument is the same for the lack of inventive findings for claims 1, 3 and 17.

The PAHLCK reference does not exclude aqueous carrier and as such the lack of novelty and inventive step for claims 1, 3 and 17 is maintained.

Claims 1, 3 and 17 lack novelty under PCT Article 33(2) as being anticipated by PAHLCK et al (US 5,320,835).

Claims 1, 3 and 17 lack an inventive step under PCT Article 33(3) as being obvious over PAHLCK et al (US 5,320,835).

PAHLCK discloses cosmetic formulation that contains rupturable microcapsules having cores that comprise dyed solid particles and the solid particles are dispersed in hydrophobic carrier (abstract and examples I-XVIII).

Claims 4-15, 18-30, 32-55 and 58-62 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a composition comprising a carrier, capsules, sensorial indicia and a mixture of phenolphthalein, nonyl phenol polyoxyethylene ethanol, tridecyl polyoxyethylene ethanol and polyethylene glycol.

Claims 1, 3-15, 17-30, 32-55 and 58-62 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed have industrial application in the cleansing art and can be made or used in industry.

7. A composition as described in claim 3, wherein said carrier comprises a mixture of water, sodium xylene sulfonate, sodium toluene sulfonate, dodecylbenzene sulfonate, dodecyl phenol polyoxyethylene ethanol, and polyacrylamide.

5 8. A composition as described in claim 2, wherein said capsules are formed from a fully hydrolyzed polyvinyl alcohol.

9. A composition as described in claim 9, wherein said fully hydrolyzed polyvinyl alcohol comprises Celvol 107.

10 10. A composition as described in claim 3, wherein said capsules are formed from vinylidene chloride-methyl acrylate copolymer.

11. A composition as described in claim 11, wherein said vinylidene chloride-methyl
15 acrylate copolymer comprises Daran 159 Latex.

12. A composition as described in claim 1, wherein said plurality of capsules comprise a plurality of non-aqueous soluble capsules.

20 13. A composition as described in claim 13, wherein said capsules are formed from polyvinyl acetate.

14. A composition as described in claim 1, wherein said plurality of capsules comprise a plurality of non-aqueous soluble capsules.

25 15. A composition as described in claim 1, wherein said capsules are formed from a capsule substance selected from the group consisting of a urea-formaldehyde, a polyvinyl acetate, a vinylidene chloride-methyl acrylate copolymer, a Daran 159 Latex, a polyvinyl methyl ether/maleic anhydride copolymer, a cellulose acetate butyrate, and a cellulose
30 acetate propionate.

16. A composition as described in claims 2, 3, 4, or 5, wherein said material within said capsules comprises trisodium phosphate.

17. A composition as described in claim 18, wherein said trisodium phosphate comprises trisodium phosphate particles between about 40 microns and about 180 microns.

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18. A composition as described in claim 18, wherein said trisodium phosphate comprises trisodium phosphate particles between about 55 microns and 180 microns.

19. A composition as described in claim 18, wherein said trisodium phosphate
10 comprises trisodium phosphate particles between about 40 microns and 55 microns.

20. A composition as described in claim 18, wherein said trisodium phosphate particles are fluid bed coated to form said capsules.

15 21. A composition as described in claim 22, wherein capsules walls have a thickness of between about 15 microns and about 50 microns.

22. A composition as described in claim 2, wherein said capsules have a range of size of between about 55 microns to about 240 microns.

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23. A composition as described in claim 6, wherein said material within said capsules comprises a sugar particle having a dye coat.

24. A composition as described in claim 25, wherein said dye coat comprises blue dye
25 #7.

25. A composition as described in claim 25, wherein said sugar particle has a size of between about 75 microns to about 125 microns.

30 26. A composition as described in claim 25, wherein said sugar particle has a size of about 100 microns.

27. A composition as described in claims 27 or 28, wherein said dye coat has a thickness of between about 15 microns and about 30 microns.

28. A composition as described in claims 27 or 28, wherein said dye coat has a
5 thickness of about 25 microns.

29. A composition as described in claim 31, wherein said oil comprises oil of
wintergreen.

10 30. A composition as described in claim 31, wherein said oil comprise methyl salicylate.

31. A composition as described in claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, or 14,
wherein said composition comprises a cleaning agent.

15 32. A composition as described in claim 34, wherein capsule rupture characteristics are altered by capsule wall thickness.

33. A composition as described in claim 35, wherein capsule rupture characteristics
20 are altered by capsule size.

34. A composition as described in claim 34, wherein capsule rupture characteristics are altered by capsule size.

25 35. A composition as described in claim 37, wherein capsule rupture characteristics are altered by capsule wall thickness.

36. A composition as described in claim 34, wherein capsule rupture characteristics are adjusted to provide delayed release of said material in response to application force
30 characteristics.

37. A composition as described in claim 35, wherein capsule wall thickness is between about 10 microns and about 30 microns.

38. A composition as described in claim 35, wherein capsule size is between about 60 microns and about 240 microns.
- 5 39. A composition as described in claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, or 14, wherein said composition comprises a hand washing agent.
40. A composition as described in claim 42, wherein capsule rupture characteristics are altered by capsule wall thickness.
- 10 41. A composition as described in claim 43, wherein capsule rupture characteristics are altered by capsule size.
42. A composition as described in claim 42, wherein capsule rupture characteristics are altered by capsule size.
- 15 43. A composition as described in claim 45, wherein capsule rupture characteristics are altered by capsule wall thickness.
- 20 44. A composition as described in claim 42, wherein capsule rupture characteristics are adjusted to delay release of said material in response to application force characteristics.
45. A composition as described in claim 47, wherein capsule rupture characteristics of said capsules are adjusted to release said material between about 5 seconds and about 30 seconds after commencement of a hand washing event.
- 25 46. A composition as described in claim 47, wherein capsule rupture characteristics of said capsules are adjusted to release of said material between about 5 seconds and about 30 15 seconds after commencement of a hand washing event.
47. A composition as described in claim 45, wherein said capsules are greater than about 100 microns in size.

48. A composition as described in claim 45, wherein said capsules are less than about 100 microns in size.

5 49. A composition as described in claim 42, wherein said perceivable sensorial indicia comprises color change of said carrier.

50. A composition as described in claim 52, wherein said discrete event comprises achievement of a therapeutic hand wash event.

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51. A composition as described in claim 52, wherein said discrete event comprises elapse of a hand wash event of pre-determined duration.

52. A composition as described in claim 52, wherein said discrete event comprises
15 elapse of a hand wash event having duration of time selected from the group of: between about 5 seconds and about 10 seconds, between about 6 seconds and 11 seconds, between about 7 seconds and about 12 seconds, between about 8 seconds and about 13 seconds, between about 10 seconds and about 14 seconds, between about 11 seconds and about 15 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9
20 seconds, about 10 seconds, about 11 seconds, about 12 seconds, about 13 seconds, about 14 seconds, about 15 seconds.

53. A method of washing hands, comprising the steps of:

- 25
- a. sequestering a material in a plurality of capsules;
 - b. conveying said plurality of capsules in a hand washing agent to a surface of at least one hand;
 - c. commencing hand washing, wherein hand washing applies hand washing forces to said capsules;
 - d. rupturing a portion of said plurality of said capsules in response to said
30 hand washing forces;
 - e. releasing said material into said hand washing agent; and
 - f. generating a perceivable sensorial indicia of completion of said hand washing with said hand washing agent.